

## Response to Concerns Regarding the ISPOR Code of Ethics for Researchers

To the Editor—Thank you for the opportunity to respond to the letter from Hope and Briggs regarding the ISPOR Code of Ethics Task Force report which was published in the March issue of *Value in Health*. Their letter raised nine points and, as chair of the Task Force, I would like to approach this by responding on a point-by-point basis. Because their letter is being published in this same issue, I will refrain from repeating each of their points in their entirety in this letter.

1. The article does note that this was an effort to build upon the work of the ISPOR Health Science Policy Task Forces and to develop a code of ethics that would be applicable to ISPOR and its members. ISPOR is a society of a diverse group of researchers, many of whom come from disciplines such as economics, epidemiology, public policy, health services research, clinical research, and others. The Task Force never intended to build a code of ethics for each discipline. Rather it intended to address the issues broadly but with as much detail as practicable. In this light, we believe that we have successfully accomplished our mission.
2. Our broader set of principles is set forth in the form of identifying the various stakeholders and how research issues affect them. The Task Force spent considerable time and debate identifying these stakeholders and their issues, and we believe that we have been most thorough. Indeed the effort was hardly arbitrary, as Hope and Briggs have suggested. Their letter does not make clear why they believe the issues covered in the Code are arbitrary.
3. ISPOR is a professional organization where members share research and related information. As such, it is not currently interested in becoming a licensing or disciplinary organization. The Code serves as a guide to its diverse membership. One must raise the issue as to how realistic any disciplinary process could be in an organization with the membership and scope of ISPOR. Hope and Briggs do not offer guidance on this issue.
4. We did review the codes of ethics of other organizations and, indeed, we did not note this

in the report. These were reviewed primarily for their structural value and not their content. Thus we did not deem it necessary, at the time, to mention our review of them in our report.

5. The Task Force was formed by the ISPOR Health Policy Committee. Each of the members of the Task Force was asked to serve, and the Task Force itself was not involved in selecting its members. Having said that, we recognized early on that we did not have representation from outside the United States. Thus the Code and the background report were sent out to at least two European ISPOR members for their review and comment. The Task Force subsequently incorporated their comments into its work. The process of open review of the Code was both lengthy and public. The Task Force conducted two open meetings on the Code, one in the United States at the Sixth Annual Meeting in 2001 and the other at the Fourth Annual European Congress in 2001. We did receive comments from the membership at both of these meetings and their comments were considered as we prepared our final report. In addition, the Code and, later, a draft background report were placed on ISPOR's website for more than 2 years and the membership was asked to provide comments. Interestingly, we did not receive even one comment from the membership as a result of the web postings.
6. We do reference the Belmont Report in the Task Force background paper. Indeed we deliberately refrained from comparing this Code to those of other organizations. In initial drafts we made note of specific ethical problems around the globe related to research and experimentation. Nevertheless, our outside reviewers suggested that it would not be appropriate for us to focus on the specific past problems of any particular country, and we felt that this was excellent advice. The Code is certainly not meant to replace any other code or guidelines. It is simply meant to offer guidance to a somewhat diverse population of researchers who have outcomes research as a primary focus. Regarding guidelines for authorship, we regret that Hope and Briggs believe that we suggest JAMA's guide-

lines be adopted by all outcomes researchers. In our background report, we note that at least one major peer-reviewed journal has adopted a checklist for authorship determinations and we cite JAMA in the references. We did not say, nor did we intimate, that this was the only source. Drs. Hope and Briggs also mentioned the issue of denial of coverage. As far as this is concerned, we felt that it goes far beyond a code of ethics for researchers. The Task Force merely raised this as a question and did not make any recommendations on this issue. The Code basically says that researchers should do good, transparent, and publishable research. This work would then serve as a basis for those who make decisions in the health-care arena. This is a code of ethics for researchers, not for health-care decision makers, and this is quite obvious in the body of work that our Task Force has produced. Thus, it is unclear as to why Hope and Briggs have suggested that we go beyond that. As far as the withholding of publication, we cite another author's point of view that it is unethical to withhold publication. The Code, itself, does not state this. Again, this is quite clear from a reading of the Code and background paper. We recognized that withholding of publication is a difficult issue, especially in light of contractual issues, and we felt that our (and ISPOR's) best contribution would be to raise awareness. In the Code itself, we do state that members should strive to publish their work. To go beyond this would be impractical,

and when even one section of a Code of Ethics is impractical, it could affect a reader's judgment of the entire Code.

7. Drs. Hope and Briggs, for some reason, have focused on our use of the word "prudent." Their suggestion appears to go far beyond any reasonable explanation of the context in which we use the term so it is difficult to respond to this point.
8. In that same light, use of another term, in this case "institutional review boards," does not control the entire code. Drs. Hope and Briggs were aware of the fact that "research ethics committee" means the same thing, and we believe other ISPOR members will not be confused over this. They do re-raise the issue of its pointing to the fact that the Code is written from a US perspective. Given our use of outside reviewers from Europe and our two open meetings, one in Europe, we disagree.
9. None of the Task Force reports were subjected for peer review by the journal. These are not research publications, but are reports of the work of committees and should be viewed as such.

We wish to thank Drs. Hope and Briggs for bringing some of these issues before the readership and we hope that we have adequately responded.—Francis B. Palumbo, PhD, JD, on behalf of the Task Force on Code of Ethics for Researchers: Francis Palumbo, Rod Barnes, Patricia Deverka, William McGhan, Lawrence Mullany, Albert Wertheimer.